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BY: Lois Dain

DATE: April 22, 2002

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of Ian Richard Anselm Peak *et al.* : Group Art Unit : 1645
Conf. No.: 6450 : Examiner: Vanessa L. Ford
Appln. No.: 09/771,382 :
Filed: January 25, 2001 : Attorney Docket : No. 8795-24U1
For: MODIFIED SURFACE ANTIGEN :

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**RESPONSE TO ELECTION/RESTRICTION REQUIREMENT
AND
PRELIMINARY AMENDMENT**

This paper is filed in response to the Election/Restriction Requirement dated March 22, 2002 (Paper No. 12).

Response to Election/Restriction Requirement

In the Election/Restriction Requirement, the Examiner included two or more separate election/restriction requirements.

In the first restriction requirement, the Examiner identified four Groups of claims, designated Groups I to IV. The Applicants elect the subject matter of the claims of **Group II** (claims 10-16), directed to isolated proteins and pharmaceutical compositions for prosecution on the merits in this application, without traverse.

In second and third requirements (second sentence in item 5 on page 3 of the Election/Restriction Requirement), the Examiner requires election of a single amino acid sequence corresponding to Group II and a single group of specific residues within that sequence. The Applicants provisionally elect the sequence **SEQ ID NO: 11**, with traverse. The Applicants also provisionally elect **residues 109-120** of SEQ ID NO: 11, again with traverse.

It is not clear to the Applicants whether the Examiner poses each of the second and third requirements as restriction requirements or election of species requirements. The Applicants contend that each of the second and third requirements should be treated as election of species requirements.

In order to set up a discussion of the reasons why the Applicants traverse the second and third requirements, the Applicants first briefly summarize the invention. The Applicants have identified conserved regions of NhhA protein and disclose that these conserved regions are useful for making vaccines that are widely applicable to *N. meningitidis* strains. The Applicants have done this by determining a consensus sequence of NhhA protein (SEQ ID NO: 11) from 10 different strains of *N. meningitidis* and identifying which regions of the consensus sequence differ among the strains (i.e., thereby identifying useful and immunologically significant regions). The Examiner purports to limit the claims to one of SEQ ID NOs: 1-11 and to a single group of residues within the sequence. The Applicants traverse these requirements for the following reasons.

The consensus sequence of NhhA (i.e., SEQ ID NO: 11) is a generic representation of the NhhA sequences (SEQ ID NOs: 1-10) of 10 different strains of *N. meningitidis*. Thus, consensus sequence SEQ ID NO: 11 is a generic representation of the 10 specific sequences SEQ ID NOs: 1-10. For this reason, the Applicants do not believe that restriction among SEQ ID NOs: 1-11 is appropriate, because elected SEQ ID NO: 11 includes each of species SEQ ID NOs: 1-10 within its scope. The Applicants respectfully request that the Examiner examine all of the elected claims as they relate to generic SEQ ID NO: 11. The Applicants do not believe that election of one of SEQ ID NOs: 1-10 (i.e., each of which is sub-generic to SEQ ID NO: 11) is appropriate at this time. However, in the event the Examiner is inclined to issue a further election of species requirement with regard to SEQ ID NOs: 1-10, the Applicants provisionally elect SEQ ID NO: 1, without traverse.

Identification of conserved regions within the consensus NhhA sequence represents an important aspect of the invention. The number of conserved regions is determined by the NhhA sequences of individual strains - not by the number of inventive acts performed by the Applicants. For this reason, the Applicants believe that identification of consensus sequence SEQ ID NO: 11 and its conserved regions was a single "invention" and that restriction among the

conserved regions is not warranted. For this reason, the Applicants respectfully contend that the third requirement should be treated as an election of species requirement.

In summary, the Applicants request that the Examiner examine on the merits:

- i) the subject matter of the claims of Group II (claims 10-16);
- ii) the subject matter of the claims of i), as they relate to SEQ ID NO: 11, which includes each of SEQ ID NOs: 1-10 within its definition (with SEQ ID NO: 1 being a provisionally elected species, should the Examiner so require); and
- iii) the subject matter of the claims of ii), first as they relate to residues 109-120 of SEQ ID NO: 11 and, if this subject matter is found to be allowable, the subject matter of the claims of ii), as they relate to each other group of residues recited in the claims.

In order to place the claims in better condition for examination in view of the requirements imposed by the Examiner, the Applicants are filing herein the substitute claims. The Applicants believe that each of claims 24-32 corresponds to each of the elections and provisional elections made by the Applicants.

Preliminary Amendment

Prior to examining the elected claims on the merits, please amend the application as follows.

In the Claims:

Please cancel claims 1-23, without prejudice to including the subject matter of the canceled claims in one or more related patent applications.

Please add claims 24-32, as follows.

--24. An isolated protein comprising at least twelve contiguous amino acids of a conserved region of SEQ ID NO: 11, wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the protein is capable of eliciting an immune response against one or more strains of *N. meningitidis*.